SUBJECT:	Fermilab Assessment Manual – Chapter 4 Independent QA Assessment Procedure – Form 2	NUMBER:	3902.1004 FORM 2
RESPONSIBILITY:	Quality Assurance Manager	REVISION:	001.4
APPROVED BY:	Head, Office of Quality and Best Practices	EFFECTIVE:	11/15/2011

Fer	milab Independent QA Assessment Report	
Assessment Number & Title:	12-QA-017 PPD – Design and Engineering	Version: 1

Date(s) of Assessment: 7/30/2012 – 8/3/2012

Performing Organization: Office of Quality & Best Practices (OQBP)

Assessed Organization(s): Particle Physics Division (PPD) including Electrical and Mechanical Engineering Departments

According to the PPD web site and persons interviewed, the Electrical Engineering Department performs design work on detector front-end electronics for experiments and astrophysics projects. They also support new experiments through consulting and infrastructure. Design Engineering is available for digital, analog, Application Specific Integrated Circuits (ASIC), controls, systems, and power supply design. Resources are available for schematics, board layouts, construction drawings, mechanical drawings, and general documentation. Fabrication support is available for circuit boards, chassis, cables, surface mount assemblies, and various modules. Testing services range from general board level testing to integrated circuit wafer level and packaged part testing.

The Mechanical Engineering Department provides engineering support to the wide variety of experiments within PPD. Examples include Finite Element Analysis (FEA), which is used for stress analysis and thermal conductivity of low radiation length materials. Fluid process engineering, which usually involves cooling or precision temperature control. High Vacuum, which is commonly associated with cryogenic insulation. Industrial process instrumentation and control systems. The department provides the entire package from wiring, Programmable Logic Controller (PLC) programming, Human Machine Interface (HMI) and web server configuration.

Assessment Activities & Scope:

Implementation and effectiveness of controls for Design and Engineering described in IQA chapter six, the Fermilab Engineering Manual (EM), and PPD requirements were examined via interview, observation, and document review.

Scope Limitations:

• PPD procurement activities and software were excluded.

Activities Reviewed Within this Assessment:

- Requirements and specification development and review
- Risk analysis development
- Design development and review
- Testing
- Release to Operations

Description of the Implementation & Effectiveness of Observed Activities:

Design and Engineering

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The requirements of IQA chapter six, Design, and the Fermilab Engineering Manual, chapters one through nine, are partially met and partially implemented within the PPD Electrical and Mechanical Engineering Departments. Two projects from each department were reviewed by the assessment team. Effective design and engineering practices were being followed by the engineers on each project, but not all requirements of the Engineering Manual were being met. All persons interviewed were aware of the Engineering Manual and its contents, but most were unaware that they were required to use it in their daily design and engineering tasks and activities. Four PPD projects were assessed:

- NOvA Rack protection (Electrical Engineering Department)
- LINAC BPM Readout (Electrical Engineering Department)
- NOvA Block Pivoter (Mechanical Engineering Department)
- MicroBooNE Cryogenics System (Mechanical Engineering Department)

The compliance of each of the projects to the requirements of the nine EM chapters is summarized in the table in Appendix One.

The assessment team verified through interviews and observation of documents and records that all projects had documented requirements and specifications (File01). However, the specifications for one of the projects were only available as email.

One of the projects had progressed past the point of Chapter two, Engineering Risk Assessment, before the EM was rolled out in July of 2010. This project completed a project risk assessment (File02). None of the other three projects completed the Engineering Risk Assessment at the beginning of the project as required by chapter two of the EM.

All projects had evidence of completed specification reviews (File03). For two of the projects there was no evidence of the review meeting minutes, attendees, and issues, as required by chapter three of the EM. For one of the projects, the review documentation records were only available in email form.

All projects had well documented designs (File04) that included documents such as drawings, schematics, Engineering Notes and calculations. Two projects also used prototypes.

There was evidence of design reviews for all projects which consisted of approved Engineering Notes (File05) and Drawings (File06). However, only two of the four projects had evidence of review meeting minutes (File07), attendees, and issues, as required by chapter five the EM. For one of the projects, the review documentation records were only available in email form.

Only three projects have progressed to the testing stage and all three have produced documented test plans and test results (File08).

The Release to Operations chapter of the EM was only applicable for one of the projects. This project had documented operating procedures (File09) meeting the requirements of the EM.

One of the four projects is complete. This project used the PPD Operational Readiness Clearance (ORC) ES&H Review of Experiments (File10) (PPD ESH 006 revision 1.1) to record Final Documentation. However, the ORC documentation addresses safety aspects and does not fulfill the requirements of a final report containing important technical decisions, maintenance procedures, and system interfaces as required by chapter nine of the EM.

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Conclusions:

Although effective design and engineering practices were used by all projects reviewed during the assessment, the requirements of the Engineering Manual have not been fully implemented within PPD. The Engineering risk assessment found in chapter two has not been performed at the beginning of projects as required. Without this review, it is not possible to determine which of the high risk requirements need to be followed for the remainder of the project. In addition, the formality of specification and design reviews used in three of the projects did not meet the EM requirement. One of the projects relied primarily on email for storing project documentation and records

Findings:

1. The requirements of the Fermilab Engineering Manual have not been fully implemented within PPD as required by Chapter six, Design, of the IQA.

The FNAL Engineering Manual, Chapter three, Requirements and Specifications Review and Chapter five, Engineering Design Review, in the Review Documentation sections state "... documentation includes, at a minimum, a meeting summary describing who attended the review, what issues they discussed, what deficiencies they identified and what recommendations they made." Three of the projects assessed did not have the required documentation for requirements or design reviews.

Chapter six section 6.2.3 states: "...all engineering, including system integration, is performed according to the provisions of the Engineering Manual." Chapter 2 of the EM, Engineering Risk Assessment, was not implemented for any of the projects assessed as a preliminary step in the project. The appropriate level of documentation and review for the remainder of the project is based on the results of the risk assessment.

Observations and Recommendations:

1. **Observation:** One of the projects assessed kept specifications and specification reviews in emails.

Recommendation: Going forward ensure that all specifications and reviews are documented according to the Fermilab Engineering Manual, chapters one and three. The Fermilab Employee Records Management Handbook, revision 11/22/2011, Electronic Records and Email section states "...the email system is not a place to store records. Email messages that meet the definition of a record should be transferred from the email system and stored on a separate server..."

Commendable Practices:

1. For two of the projects, part number, drawing number, revision number, and date are clearly displayed on hardware assemblies. This is beneficial when incorporating project-specific modifications to a current design (as was done in at least two of the projects) and for legacy troubleshooting.

Persons Interviewed:

• Sten Hansen

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- David Huffman
- Jim Kilmer
- Ang Lee
- Mike Matulik
- Dave Pushka
- Justin Tillman
- Ernie Villegas
- Mike Zuckerbrot

Documents Reviewed:

- PPD_ESH_006 Operational Readiness Clearance ES&H Review of Experiments, revision 1.1, 7/20/2012
- FESHM Chapter 5031, Pressure Vessels, revision 05/2012
- FESHM Chapter 5031.1, Piping Systems, revision 11/2007
- FESHM Chapter 5032, Cryogenics System Review, revision 01/2011
- FESHM Chapter 5034, Pressure Testing, revision 03/2009

Attachments:

- File01-pivoter-reqs.pdf
- File02-blockpivoter-riskanalysis.pdf
- File03-BPM-regsrev.pdf
- File04-MicroBooNE-Piping-Diagram.pdf
- File05-eng note 423 NOvA Pivote-Pusher.pdf
- File06-appr-pivoter-drawing.pdf
- File07-pivoter-des-rev.pdf
- File08-eng_note_423_NOvA_Pivoter Pusher-test-data.pdf
- File09-blockpivoter-operatingproc.pdf
- File10-RackProtectionpORCSignatureSheet.pdf

Standards, Regulations, and Other Program Requirements Applied:

The specific criteria applied to this assessment were:

- 1001, IQA revision two, Chapter six, Design
- Fermilab Engineering Manual revision 7/10

Corrective Action Plans Issued:

PD-20120817-01

Assessors' Names (asterisk indicates team leader):

- John Martzel* OQBP
- Don Rohde Accelerator Division (AD)
- Q. Tracy Sims Department of Energy (DOE), Office of Science Chicago Office (SC CH)

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Date: 8/17/2012 **Submitted by:** John Martzel Distribution (Distribute to assessed organizations' management, OQBP head, and other interested parties): Mike Lindgren Jed Heyes Erik E Gottschalk John Martzel Peter Wilson Don Rohde Karen Kephart Berline Short Eric James Q. Tracy Sims Kurt Krempetz Marcus Larwill J. J. Schmidt

Appendix 1 – PPD Project Compliance to the Engineering Manual Requirements

PPD Engineering Manual Compliance				
Engineering Manual Chapter	Project A	Project B	Project C	Project D
Requirements and Specifications	N/A1	А	В	Α
2. Engineering Risk Assessment	N/A1	С	С	С
3. Requirements and Specifications Review	N/A1	А	В	А
4. System Design	Α	Α	А	Α
5. Engineering Design Review	Α	Α	В	В
6. Procurement and Implementation	N/A2	N/A2	N/A2	N/A2
7. Testing and Validation	А	N/A3	Α	А
8. Release to Operations	Α	N/A3	N/A4	N/A3
9. Final Documentation	N/A3	N/A3	В	N/A3
A - fully compliant				
B - partially compliant				
C - not compliant				
N/A1 - completed prior to EM official				
N/A2 - outside assessment scope				
N/A3 - project has not completed chapter				
N/A4 - chapter not applicable for this project				